

Remarks

Claims 1-34 are pending.

Claims 4-6, 11-12, 15-18, 23-26, 28-34 are cancelled.

Claims 7, 13-14, 19-22, and 27 have been withdrawn from consideration

Claims 1-3 and 8-11 are rejected.

The amendments to claims 1 and 3 that recite carcinogen-induced foci formation in mammalian cells (C3H 10T1/2 mouse embryo fibroblast cells) is supported in the specification at page 2.

The genus and species claim elections have been made. Applicant elected Group I, and combination of the following 20 genes:

ADAM9

BUB1B

Gene 85 (also called "CD44")

CD46

GJA1

HIF1A

ITGB1

LAMB1

MAD2L1

Gene 13 from Table 1 (FLJ20373)

Gene 98 from Table 1 (Formin binding protein 3, also called FBNP3 – See Table 1)

PSMC6

RANBP2

Gene 58 from Table 1 (also called "CSPG6" or "SMC3")

SP3

THBS1

TTK

PRKAR1A

TOB1

Gene 73 from Table 1 (called “Acidic (leucine-rich) nuclear phosphoprotein 32 family, member E”).)

Claim Objections

Claims 1-3 and 8-11 are objected to because they reference the tables. The claims have been amended to reference the individual genes.

Rejections under 35 USC 112 first paragraph

Claims 1-3 and 8-11 are rejected as failing to comply with the enablement requirement. In particular Gene 85 (CD 44) appears to lack enablement in the specification as Table 1 describes this gene as “Data not available”. Gene 85 has been deleted from the claimed gene set.

Gene 13 is listed in Table 1 as the gene for the “hypothetical protein FLJ20373”. The claims have been amended to recite “the gene encoding FLJ20372”. Reference to “MAP4K4” has been removed. It is hoped that this provides sufficient enablement as it can refer only to a specific gene, whether hypothetical or not, and therefore unequivocally identifies the gene so as to clearly limits the claim to including this gene.

Gene 98 from Table 1 is referred to in the amended claims only as “Formin binding protein 3” and reference to “PRPF40A” has been removed.

Gene 58 from Table 1 is referred to in the amended claims only as “CSPG6” and reference to “SMC3” has been removed.

Breadth of claims

The examiner objects to the breadth of the claims in view of the unpredictability. In particular the examiner suggests that a claim is overbroad that claims a method wherein the degree of increase in expression of various genes upon exposure to a test compound corresponds to the degree of antineoplastic activity of the test compound. The examiner

suggests that the word “corresponds” means “is similar to or in agreement with”. The applicant would like to state that it regards the term “corresponds to” as meaning “is associated with” or “is indicative of”, therefore the claims is meant to define a method where an increase in expression of various genes upon exposure to a test compound is indicative of the degree of antineoplastic activity of the test compound.

The problem of unpredictability is compounded by the fact that the original claims broadly recited “providing a cell” and measuring gene expression before and after exposure to a test compound. The claims have been amended to recite exposing not any cell, but RWPE-1 and RWPE-2 cells to the test compound.

Nature of the invention (page 7 et seq.)

The examiner cites the unpredictability of the art and states that the art of determining an association between gene expression levels and the occurrence of a phenotype, such as response to therapy is highly unpredictable. The claims, therefore, have been amended to recite a much narrower invention, one in which the coordinate expression of a set of specific genes within a specific cell type, corresponds not to anti-neoplastic activity of a compound in general, but to a compound that has the property of suppressing chemically-induced carcinogenesis in mammalian cells.

As the examiner points out [para. 1] “the specification teaches that the compound lunasin suppresses chemically-induced carcinogenesis in mammalian cells and suppresses skin tumor formation in mice...”. This the effect of the claimed coordinate up-regulation is well supported by scientific evidence and reasoning as enabled by the specification.

Further (pg. 9) the examiner states that “it is unpredictable as to whether the results obtained with a single immortalized human prostate cell line in vitro would be predictive of results obtained in other cancer and non-cancer cell lines or primary cell lines.” The applicant has therefore amended the claim to recite using only the RWPE cell line actually used in the experimental examples disclosed in the specification.

Amount of Direction of Guidance (pg. 13 et seq.)

The examiner states that there is insufficient guidance to allow one of skill to extrapolate the results obtained from using RWPE cells to any other cancer or non-cancer cell. As above, the applicant has amended the claim to recite using only the RWPE cell line actually used in the experimental examples disclosed in the specification, thereby traversing the rejection.

Rejections under 35 USC 112 second paragraph (pg. 16 et seq.)

Claims 1-3 and 8-11 are rejected as indefinite. The examiner points out that the claims recite a method for screening a test compound wherein an increase in gene expression “corresponds to” the degree of antineoplastic activity of the compound. The examiner states that such a recitation indicates only an inherent property and “is not equivalent to reciting a step that determines whether a test compound does or does not have neoplastic activity.” In view of this the claims have been amended not to recite a method for identifying a test compound having anti-neoplastic activity in general, but to identifying a compound that has the property of suppressing chemically-induced carcinogenesis in mammalian cells. It is believed that the functional correspondence between up-regulation for the specific named genes (by at least 100%) in the specific RWPE cell line and the property of suppressing chemically-induced carcinogenesis in mammalian cells is well enabled in the present specification and is sufficiently predictable such that one of skill in the art could confidently practice the claimed invention.

Priority (pg.19 et al.)

The applicant acknowledges that the ‘288 application cannot in all respects claim priority to the 60/549,487 application since the earlier application does not include all the genes of Table 1.

Rejections under 35 USC 102 (pg.19 et al.)

Claims 1-3 and 8-11 are rejected as anticipated by Li et al. The claims have been amended to recite a method for identifying a test compound that has the property of suppressing chemically-induced carcinogenesis in mammalian cells, the method

comprising providing (a) RWPE-1 and RWPE-2 cells, (b) measuring expression by the cell of 19 specific genes, (c) exposing RWPE-1 and RWPE-2 cells to the test compound, (d) re-measuring the expression of the named genes by the cells after exposure, (e) comparing the expression of the named genes in RWPE-1 with the expression of the named genes in RWPE-2, wherein a coordinated increase in expression of all of the above genes indicates that the test compound has the property of suppressing chemically-induced carcinogenesis in mammalian cells. Li et al does not teach or suggest the combination of all these elements to identifying a test compound that has the property of suppressing chemically-induced carcinogenesis in mammalian cells.

In view of the present amendments it is believed that the rejections are overcome. The presently amended claims recite a method for identifying a test compound that has the property of suppressing chemically-induced carcinogenesis (foci formation) in mammalian cells wherein the method measures differential expression of specific named genes in RWPE-1 and RWPE-2 cells. The claims are fully supported by the specification and no new matter is added.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'A. Bell', enclosed within a circular scribble.

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